

REMARKS

The Office Action dated May 23, 2008 has been received and reviewed. Claims 1 to 15 are pending in the application. Claims 1, 4, 6-8, 10, and 12-15 are currently amended. Reconsideration of the application is respectfully requested.

Claim Objections

Claims 4-15 are objected to under 35 CFR 1.75(c) as being in improper form because a multiple dependent claim may not serve as a basis for any other multiple dependent claim. Claims 4, 6-8, 10, and 12-15 have been amended to eliminate multiple dependent claims that serve as a basis of other multiple dependent claims. Applicant believes that the claim dependencies are now in proper form and requests withdrawal of the objection under 35CFR 1.75(c).

Rejections under 35 USC 102

Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Zolopa et al. (Ann Intern Med 1999; 131:813-821). Applicant has amended claim 1 to include the feature wherein determining the effect of one or more antimicrobial(s) comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of microorganisms in the sample at the end of the pre-determined time period. Support for the amendment “adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period, and assessing the number of microorganisms in the sample at the end of the pre-determined time period” can be found on page 4, lines 30-34 of the specification. Support for the amendment “under conditions that allow some growth of the micro-organism” can be found on page 10, line 37.

Applicant's specification clearly delineates, with respect to clinical samples, that samples include “Specimens *taken from* patients” (emphasis added). Therefore, incubating a micro-organism from the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism necessarily would occur outside a patient. Zolopa discloses treating a patient infected with HIV-1 with

an antiretroviral drug. Thus, the exposure of the virus to the antiviral drug under conditions that allow for the growth of the virus only occurs in the patient. There is no teaching or suggestion in Zolopa et al of incubating a micro-organism outside a patient in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism. In view of the amendment to claim 1, the rejection of claims 1-3 as being anticipated by Zolopa et al is moot.

Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Kain et al. (Am. J Trop. Med. Hyg. 49:478-484, 1993). Applicant has amended claim 1 to include the feature wherein determining the effect of one or more antimicrobial(s) comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of microorganisms in the sample at the end of the pre-determined time period. Kain et al teaches drying the samples on filter paper. There is no teaching or suggestion in Kain et al of incubating the sample in the presence of an antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism. In view of the amendment to claim 1, the rejection of claims 1-3 as being anticipated by Kain et al is moot.

Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Troesch et al. (Journal of Clinical Microbiology, Jan. 1999, p. 49-55). Applicant has amended claim 1 to include the feature wherein determining the effect of one or more antimicrobial(s) comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of micro-organisms in the sample at the end of the pre-determined time period. Troesch et al teaches testing for rifampin resistance by a proportional method involving the growth of each isolate in antibiotic-containing medium compared with the growth of the isolate on the drug-free medium. Troesch et al further teaches that, after testing for rifampin resistance, the fresh colonies of the organisms are grown, the total nucleic acid is released from the freshly-grown bacteria, and specific antibiotic gene markers are identified in the total nucleic acid by PCR and hybridization. There is no teaching or suggestion in Troesch et al of determining

the effect of one or more antimicrobial(s) by a process including adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of micro-organisms in the sample at the end of the pre-determined time period, wherein said assessing the number of micro-organisms in the sample is performed by analyzing the micro-organism's nucleic acid. In view of the amendment to claim 1, the rejection of claims 1-3 as being anticipated by Troesch et al is moot.


Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Rustad et al. (Microbiology 148:1061-1072, 2002). Applicant has amended claim 1 to include the feature wherein determining the effect of one or more antimicrobial(s) comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of microorganisms in the sample at the end of the pre-determined time period. Rustad et al teaches antibiotic (fluconazole) susceptibility testing using a standard broth dilution protocol. The Rustad et al document is silent on whether the antibiotic susceptibility testing includes analyzing the microorganisms' nucleic acid. Rustad et al further teaches that, to prepare the single-colony inocula for DNA and CHEF block preparation, the organisms are grown in YEPD medium (which is not disclosed to contain an antimicrobial). There is no teaching or suggestion in Rustad et al of determining the effect of one or more antimicrobial(s) by a process including adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of micro-organisms in the sample at the end of the pre-determined time period, wherein said assessing the number of micro-organisms in the sample is performed by analyzing the micro-organism's nucleic acid. In view of the amendment to claim 1, the rejection of claims 1-3 as being anticipated by Rustad et al is moot.

In summary, the amendment to claim 1 has rendered moot the rejections of claims 1-3 under 35 CFR 102(b) as being anticipated by Zolopa et al, Kain et al, Troesch et al, and

Rustad et al. Applicant requests withdrawal of the rejections and reconsideration of the application.

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 736-7430. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,



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MGW:jlh#518355 Amendment to OA dated 5-23-08
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